UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
TRENTON DIVISION

HELSINN HEALTHCARE S.A.,and ROCHE PALO ALTO LLC,	) Docket No. 3:11-cv-03962-MLC-DEA) (Consolidated)
Plaintiffs,	)
versus	) Courtroom No. 6W) Clarkson S. Fisher Building
DR. REDDY'S LABORATORIES INC., DR. REDDY'S LABORATORIES LTD, SANDOZ INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	) & U.S. Courthouse) 402 East State Street) Trenton, New Jersey 08608
Defendants.	) July 30, 2014) 11:40 A.M.

TRANSCRIPT OF TELEPHONE CONFERENCE
BEFORE HONORABLE DOUGLAS E. ARPERT
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

For Helsinn Healthcare S.A.:	Saul Ewing LLP By: CHARLES M. LIZZA, ESQ. WILLIAM C. BATON, ESQ. One Riverfront Plaza, Suite 1520 Newark, New Jersey 07102-5426 Paul Hastings LLP By: ERIC W. DITTMANN, ESQ. 75 East 55th Street New York, NY 10022
ESR/Courtroom Deputy:	Charmaine Ellington
TRANSCRIPTION SERVICE:	**TRANSCRIPTS PLUS, INC.** **435 Riverview Circle** **New Hope, Pennsylvania 18938** **Telephone: 215-862-1115** **Facsimile: 215-862-6639** **e-mail CourtTranscripts@aol.com**

Proceedings recorded by electronic sound recording, transcript produced by transcription service.

APPEARANCES
(Continued)

For Teva Pharmaceuticals Industries, Ltd:	Lite DePalma Greenberg, LLC By: MAYRA VELEZ TARANTINO, ESQ. Two Gateway Center, Suite 1201 Newark, New Jersey 07102 Winston & Strawn LLP By: JOVIAL WONG, ESQ. 1700 K Street, N.W. Washington, D.C. 20006-3817
For Dr. Reddy's Laboratories, Inc., *et al.*:	Budd Larner, PC By: STUART SENDER, ESQ. MICHAEL IMBACUAN, ESQ. 150 John F. Kennedy Parkway Short Hills, New Jersey 07078-2703
For Sandoz, Inc.:	Hill Wallack, LLP By: ERIC ABRAHAM, ESQ. 202 Carnegie Center CN 5226 Princeton, NJ 08540 Morrison & Foerster LLP By: MATTHEW D'AMORE, ESQ. JAYSON COHEN, ESQ. 250 West 55th Street New York, NY 10019-9601

TRENTON, NEW JERSEY JULY 30, 2014 2:48 P.M.

(Call to order of the Court)

THE COURT: Hello, good morning.

UNIDENTIFIED ATTORNEY: Good morning, Your Honor.

UNIDENTIFIED ATTORNEY: Good morning, Your Honor.

THE COURT: This is counsel on the Helsinn DRL case?

UNIDENTIFIED ATTORNEY: That's correct.

THE COURT: And who's on for Helsinn, please? Enter your appearances.

MR. LIZZA: Sure, Your Honor. Charlie Lizza and Bill Baton of the Saul Ewing law firm.

THE COURT: Good morning.

MR. DITTMANN: And, good morning, Your Honor. This is Eric Dittmann from Paul Hastings, also on behalf of Helsinn.

THE COURT: Good morning, Mr. Dittmann.

And who wants to be heard for DRL?

MR. SENDER: Stuart Sender and Michael Imbacuan.

THE COURT: Good morning, Mr. Sender, Mr. Imbacuan. Okay.

MR. IMBACUAN: Good morning, Your Honor.

THE COURT: Good morning. And who else is on the line this morning?

MS. TARANTINO: Good morning. For Teva is Mayra Tarantino from Lite DePalma Greenberg, LLC. And joining me is Jovial Wong from Winston & Strawn.

THE COURT: Good morning, Ms. Tarantino. Okay. And who else? Someone from Sandoz, I assume?

MR. ABRAHAM: Yes, Judge, good morning. This is Eric Abraham from Hill Wallace. And I also have Matthew D'Amore and Jayson Cohen from Morrison Foerster.

THE COURT: Good morning, Mr. Abraham.

MR. ABRAHAM: Good morning.

THE COURT: Other than some housekeeping, which we'll get to in a minute, the item on my agenda for this morning is defendants' request that the Court compel Helsinn to produce a witness for a 30(b)(6) deposition on certain identified topics in their notice which -- to which plaintiff has objected based, in large part, on the parties' agreement not to conduct duplicative discovery and, in more specific terms, the Court's order -- joint stipulation and order consolidating these actions which was entered on May 29th. The specific provision of which states that the parties agree to limit fact discovery to new infringement, validity, and enforcability issues raised by the asserted claims of the '219 patent. And the essential difference, as far as I can telling having read the parties' joint submission dated July 3rd, is whether the topics and subject matter of the proposed 30(b)(6) deposition is within the parameters agreed to by the parties and ordered by the Court, that being new infringement, validity, and enforcability issues raised by the '219 patent. Defendants taking the

position that it is new; plaintiff taking the position that this is more of the same, which has been exhaustively discussed at a series of over a dozen prior depositions, and contending that defendants can point to nothing new here to substantiate the present request.

Mr. Dittmann, have I captured the essence of the issue? And is there anything more you want to say on the subject?

MR. DITTMANN: I think you've captured the essence, Your Honor, yes. And I'd be happy to elaborate, but I think Your Honor seems to have a very good handle on the dispute between the parties.

THE COURT: Okay. Well, I appreciate that.

How about from -- how about from the defendants' perspective? Let me be a little more pointed: What are the plaintiffs missing here? And I'll even tip my hand a little bit, what am I missing here having fairly extensively reviewed the language of the '219 patent and the lead patents, I'm having a hard time seeing the areas of difference about which you seek to inquire.

MR. D'AMORE: Your Honor, this is -- thank you for your question. This is Matthew D'Amore from Morrison & Foerster for Sandoz.

I'm actually going to turn the microphone over to my associate, Jayson Cohen, who you haven't spoke with yet, and I

wanted to introduce him, and then let him answer Your Honor's question --

THE COURT: All right.

MR. D'AMORE: -- if that's all right.

THE COURT: Thank you. Good morning, Mr. Cohen.

MR. COHEN: Good morning, Your Honor. This is Jayson Cohen for Sandoz.

I wanted to speak directly to Your Honor's question. I think one way to frame this is if we -- if you have the July 3rd letter in front of you, what was submitted as Exhibit G to that letter, I think there's a numbering issue in the exhibit book. What was submitted as Exhibit G was a chart of the different claims that have been asserted against the defendants.

THE COURT: Okay. I'm with you.

MR. COHEN: So I wanted to -- so on Page 3 of that exhibit, the claims for the '219 patent. And what we've done here is we've highlighted the terms that are unique -- the new terms that are unique to the '219 patent. And our -- our view is that, number one, we have promised not to repeat discovery from the first case, and I think we've stuck with that so far. And, in fact, we have not noticed any depositions of people who were deposed in the first case, et cetera.

In looking here at Page 3 of Exhibit G, we've highlighted the new claim elements in the '219 patent. And

it's really -- our 30(b)(6) deposition notice is really directed at these new elements of the claim. And the deposition testimony that we want is to get specifically plaintiffs' knowledge and positions with respect to, for example, the conception and reduction to practice of the new aspects of these claims that do not appear in the first -- in the claims of the first three patents.

And so I guess sort of to frame this further, you know, this patent was filed only as of May 23rd, 2013. At that point in time, fact discovery on the first three patents had closed. And that's just when the -- that's just when the patent application was filed. It didn't issue until December, 2013. It wasn't asserted against us until February of 2014.

So there was no point in the first case where the parties or the defendants had any reason to believe that they need to focus discovery on the new claim elements that only appeared once the '219 patent issued.

And so let me -- as I said, Your Honor, let me directly -- direct you to Exhibit B of the letter, which are the -- which are the topics, and specifically on Pages 7 through 9. And I'd like to group together certain of these topics. Topics 1 through 5, 7 and 8. So, six of the seven topics at issue here are really focused on the conception and reduction to practice and the development of the newly created inventions in the '219 patent.

And to the extent Your Honor feels that we haven't narrowed this sufficiently to focus only on those new claim elements, we're certainly willing to do so today.

But we -- our intent here is really to get plaintiffs' knowledge, get their positions on the new claim elements. Let me take a couple of the claim elements, in particular, that are important to this case:

For the first time in the '219 patent, the patent's claiming the amount of the active ingredient of the product. In the previous three patents, the amount in the product was not actually a limitation of the claims. And so this further narrows the claims from what was at issue in the first three cases, but it also changes the focus on -- of discovery to that specific dose, and how that was -- how it came about. What the -- who, what, when, where, and why with respect to specifying a specific dose of the active ingredient. And that wasn't necessary in the first case.

A second element here is in the preamble, the plaintiffs are claiming that the limitation -- or the language that says, "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting."

Their -- plaintiffs are taking the position that that's a claim element of the claim, their claim (indiscernible) of the claim and that element does not appear

in any of the previous patents.

And how that really gets translated into discovery in this case is the parties in this first case did not have to focus on specifically this claim element, and specifically the work relating to showing "intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting." And so our topics, 1 through 5, 7, and 8, are geared towards discovery information specifically about that element.

And so these are really -- we feel these are plain vanilla topics, they're not broad topics. And specifically with respect to, you know, the development of their claimed invention and the conception and reduction to practice of those claim elements, and so that's why we feel we're entitled to -- we believe we're entitled to get that discovery as to those new claim elements.

In addition to being related to our on sale bar defense in this case, these specific topics, 1 through 5, 7, and 8, also relate to the obviousness defense. Because now the issue -- when did information become publically available? Specifically about -- for example, the dose of palonosetron that would be effective specifically to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting.

And so, you know, it's with that in mind that we're seeking the depositions.

THE COURT: Let me ask --

MR. COHEN: There's only one more -- go ahead, Your Honor.

THE COURT: Let me ask you whether these are issues or subjects which could be addressed in the -- by the experts in this case, rather than additional fact depositions.

MR. COHEN: With respect to the Helsinn's knowledge as to what happened when, and who was involved, you know, we believe that that's -- that's really knowledge that's specific to the plaintiffs. It's fact information that their experts might use, but it's still information that comes from Helsinn and doesn't -- isn't generated by their experts.

THE COURT: How -- what is your projection of the duration of this deposition? How long is it going to take you to cover this limited field of information?

MR. COHEN: We had hoped to receive from Your Honor a seven-hour deposition on all the topics.

THE COURT: Okay.

MR. COHEN: So we felt we could easily finish this within a day. We're not asking for a multiple day deposition here.

And we're not asking for individual fact witnesses on this. We have our -- we're --

THE COURT: Yeah.

MR. COHEN: We've decided to streamline this case to

that only for a 30(b)(6) deposition.

I'd like to mention the last topic, Your Honor, because the last topic is also a very common topic in patent litigation, Topic 4, which is on the patent prosecution. And the way this topic is listed in Exhibit B here on Page 7, we've already narrowed this. And while we've offered it -- we're only interested in the patent prosecution for this patent and suit and its immediate parent application because there are strong ties between those two.

But this -- the (indiscernible) patent family is very big here now, and we're not asking for discovery on all of that. Only those two patent prosecutions.

And this is directly relevant to our equitable defenses in the case. We have set forth the basis for our equitable defenses in answering plaintiffs' interrogatories. And asking about having a 30(b)(6) witness from plaintiff to ask him about the patent prosecution is meant to provide information that we believe is relevant to our equitable defenses in the case.

THE COURT: All right. Thank you.

MR. COHEN: And with that, Your Honor -- yes?

THE COURT: Yeah, with that, go ahead. Conclude. I'm sorry, I cut you off.

MR. COHEN: I'm sorry. Your Honor, I think that basically we believe that getting this 30(b)(6) deposition is a

very streamlined efficient way to get the basic discovery that we believe we need in the case with respect to those new patent claim elements in the '219 patent.

And with that, Your Honor, I'll, you know, hand it back to you. And if you have any questions, I'd be happy to answer them.

THE COURT: Thank you, Mr. Cohen. Mr. Dittmann, based on what you heard today from Mr. Cohen, do you want to respond to the suggestion that these are new claim elements in the '219 patent, very limited and discreet inquiry into those subjects or those claim elements along the lines that Mr. Cohen suggested, all of which can be done with a single witness in a single day?

MR. DITTMANN: Sure. No, I would be happy to, Your Honor.

I guess there -- the first point about a single witness in a single day, and these are some disparate topics, some are referring to the confidential work that Helsinn had done over the course of five, six years. And others are referring to legal prosecution documents where the scientists that were involved in the work wouldn't -- not really much of a connection to the recent prosecution events. So that's sort of the first issue.

But to address the claims themselves, as we set forth in Footnote 8 of the joint letter, these are not new claim

elements. These are elements that directly correlate to Helsinn's marketed product, Aloxi. That's really been the focus of discovery from day one in this case, and has been the central focus of defendants' on sale bar defense. And defendants admit on Page 4 of the letter that they've already had a corporate deposition testimony with respect to Helsinn's marketed product. That's the product that has a 0.25 milligrams dose amount to five milliliter volume. And, in fact, that deposition took 1.5 days. If you'll remember, Your Honor, last year you suggested a compromise, and we ended up offering Dr. Calderari for both the entire day Friday, and part of the day Saturday, and he was extensively questioned. And we cited some exemplary portions of that testimony where he was squarely asked about the five milliliter volume, the 0.25 milligram dose, how those were determined, who determined them. This is extensively discovery in the first case. And really this is a lot about fairness. You know, we came to defendants and we gave up two patents, these two process patents. Where the patents the defendants had focused on originally to say they needed fact discovery because the processes were somewhat new we said, okay, well, look, we want to move this forward. We will give you the two patents, which is, frankly, you know, quite a lot to give in any case. And more than that, we also reduced the asserted claims to all of the patents, including the original patents, in half.

And as part of the exchange, we received defendants' commitment to limit discovery to new issues. And all we're hearing about is well, there are some new claim elements. Which, first of all, we don't agree with, Your Honor.

But even if there were any parts of the claims that are new that -- new issues is not the same as new claims. And really what defendants are attempting to do is to get a second bite at the apple on the original on sale bar defense which, by the way, their invalidity contentions show exactly the same. They focused on the same formations, the same alleged sale transaction, nothing has changed there.

And really what we're talking about is the same set of facts defendants already have. There's nothing new, Your Honor. We have nothing more to tell them about our development of this Aloxi invention.

The -- what they're seeking is precisely what Your Honor foreshadowed, is this is really about extra discovery. It's applying those facts to new claim elements, that's what experts are for. Fact witnesses aren't going to talk about claim limitations. They're going to talk about what they did, and we've already done that.

They've deposed the inventors. They've gotten Dr. Calderari as a 30(b)(6) witness for a day and a half, and they've had exhaustive discovery on all of these new claim elements.

And briefly with respect to obviousness, we heard something about information, and they want to know when information became publicly available. That has nothing to do with the 30(b)(6) topics they're asking about, which is Helsinn's confidential work. Which, by the way, as we pointed out in Footnote 11 of the letter, is irrelevant as a matter of Federal Circuit law.

But really the point is that they received this discovery, an extensive amount, so it violates the parties' original agreement in March to avoid duplicative discovery. But then more than that, we then had an agreement after agreeing not to duplicate discovery. And as part of that agreement, we gave valuable consideration. And really the -- what we obtained from that was the consolidated schedule and the agreement to limit fact discovery. And that would be eviscerated by having to go through another seven-hour deposition which, again, could never cover -- one deposition could never cover all of these topics which is a problem, number one.

And, number two, the witness who would have to address these topics is not available until mid-September because of holiday plans, Helsinn shutdown in August, and his commitments as President of the company upon his return.

But then very briefly on the last point, the prosecution topic, you know, first of all, this is the first

we've ever heard from defendants essentially justifying why this very broad topic is relevant to anything. They're mentioning their equitable defense, which we just received a description of in an interrogatory response about a week or so ago.

But the problem with this, Your Honor, is a deposition on the prosecution documents would be very wasteful. Other than the documents themselves, the work that led to them is going to be privileged. And these depositions, inevitably, end up in a number of instructions not to answer for privileged reasons. And for that reason, in the original case, defendants have an identical topic on prosecution events, and the parties agreed that there would be no need for a 30(b)(6) topic on this. And we submit again that, you know, this would be a wasteful separate deposition that would be needed.

And I think, Your Honor, I believe I've addressed the points that you were interested in. But I'd be more than happy to address any further questions you have.

THE COURT: I appreciate that. Anybody else want to be heard?

(No audible response heard)

THE COURT: Okay. I am -- I'm going to deny the defendants' request for this additional deposition of a 30(b)(6) witness on the topics that are set forth in the defendants' notice.

I largely adopt the plaintiffs' position as articulated, both in the letter of July 3rd, and by Mr. Dittmann on this call, that while Mr. Cohen has pointed perhaps to arguably new claim elements in the '219 patent, these are not new issues. These are issues which have been exhaustively, as I said earlier, discovered through at least a dozen depositions in this case.

Moreover, I think to the extent there are nuances for arguments to be made related to the '219 patent, that those nuances or differences can be addressed in the course of expert discovery.

The Court has the authority to manage discovery to the end of the case to be prosecuted efficiently, economically, and fairly. And I believe that in the totality of the circumstances presented here, that the limitation established by the parties' agreement and incorporated into the Court's case management order of May 29th limiting additional discovery to new issues is not met by the request for this deposition. So I would deny the request to compel that deposition.

The housekeeping matter to which I referred earlier comes in a letter dated July 28 with a series of modifications to the existing case management schedule. And I've reviewed those. They are all relatively modest, and I will sign that order today and include a series of telephone status conferences. I'll review the prior order, and either adopt the

dates that were already on that order or modify them. But we'll operate henceforth from the proposed schedule attached to the July 28th letter. Okay? Today's the 30th, I'll sign it now.

MR. LIZZA: Your Honor --

THE COURT: All right.

MR. LIZZA: -- this is --

THE COURT: Are there any other -- go ahead.

MR. LIZZA: Your Honor, Charlie Lizza here.

Just, again, along the lines of housekeeping, I think we have a schedule -- telephone conference in August, and I assume that this order now will supersede the need for that conference.

THE COURT: Unless anybody thinks differently, that was my plan. I will vacate -- I'll essentially vacate the prior schedule with respect to conferences. And the new schedule will be reflected on the order that I'm signing today. Okay?

MR. LIZZA: All right.

THE COURT: All right. So you can clear your calendars of any earlier dates, and -- and refer exclusively to the dates that will be included on Page 3 of the order that I'm going to sign and enter today. Okay?

(No audible response heard)

THE COURT: All right. Any --

UNIDENTIFIED ATTORNEY: Thank you, Your Honor.

THE COURT: All right. Anything else then for today, folks?

(No audible response heard)

THE COURT: All right. Thank you. Enjoy the rest of the summer. I'll speak to you sometime in the fall, unless you need me in the meantime, in which case, you know where to find me.

Thank you.

UNIDENTIFIED ATTORNEY: Thank you, Your Honor.

THE COURT: All right.

UNIDENTIFIED ATTORNEY: Thank you, Your Honor.

UNIDENTIFIED ATTORNEY: Thank you.

(Whereupon, at 12:06 P.M., the hearing was adjourned.)

CERTIFICATE OF TRANSCRIBER

I, KAREN HARTMANN, a certified Electronic Court Transcriber, certify that the foregoing is a correct transcript from the electronic sound recording of the proceedings in the above-entitled matter.

Karen Hartmann, AAERT CET**D0475 Date: August 11, 2014

TRANSCRIPTS PLUS, INC.